

JAN 25 2011

510(k) Summary for Dimension Vista® ENZ 2 CAL KC321

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K103612

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Siemens Healthcare Diagnostics, Inc.
500 GBC Drive
Newark, DE 19714

Contact Information: Siemens Healthcare Diagnostics, Inc.
500 GBC Drive
Newark, DE 19714
Attn: A. Kathleen Ennis
Tel: 302-631-9352
Fax: 302-631-6299

Preparation date: December 1, 2010

2. Device Name: ENZ 2 CAL (KC321)

Classification: Class II (21CFR862.1150)

Product Code: JIX;

Panel: Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dimension Vista® ENZ 2 CAL (KC320) k061390

4. Device Descriptions:

ENZ 2 CAL is a liquid, multi-analyte, bovine serum albumin based product containing alanine aminotransferase and aspartate aminotransferase from porcine heart.

5. Device Intended Uses:

Dimension Vista® ENZ 2CAL (KC321)

The ENZ 2CAL is an *in vitro* diagnostic product for the calibration of the alanine aminotransferase (ALT and ALT I) and aspartate aminotransferase (AST) methods on the Dimension® Vista system.

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista® ENZ 2 CAL (KC321), is substantially equivalent to the Dimension Vista®

SIEMENS

ENZ 2 CAL (KC320). Like the predicate, ENZ 2 CAL is an *in vitro* diagnostic product intended to be used for the calibration of alanine aminotransferase, and aspartate aminotransferase assays.

7. Comparative Features Table

Feature	Current Dimension Vista® ENZ 2 Calibrator KC320	Modified Dimension® Vista ENZ 2 Calibrator KC321
Similarities		
Form:	liquid, bovine serum albumin based	liquid, bovine serum albumin based
Constituents:	aspartate aminotransferase and alanine aminotransferase from porcine heart	aspartate aminotransferase and alanine aminotransferase from porcine heart
Traceability of constituents:	ALT and AST traceable to Master pool, Dimension® clinical chemistry system values	ALT and AST traceable to Master pool, Dimension® clinical chemistry system values
Packaging:	ENZ 2 CAL is packaged in glass vials containing 1.5 mL/vial. Each carton contains 3 vials of each level.	ENZ 2 CAL, modified is packaged in glass vials containing 1.5 mL/vial. Each carton contains 3 vials of each level.
Levels:	2	2
Stability and storage	ENZ 2 CAL is stored at 2 to 8° C	ENZ 2 CAL is stored at 2 to 8° C
Differences		
Intended Use:	ENZ 2 CAL is an <i>in vitro</i> diagnostic product for calibration of the Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT) methods on the Dimension Vista® System.	ENZ 2 CAL is an <i>in vitro</i> diagnostic product for calibration of the Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT and ALTI) methods on the Dimension Vista® System.
Traceability of constituents:		ALTI is traceable to the IFCC ALT@ 37°C primary reference method.

8. Conclusion

Dimension Vista® ENZ 2 CAL, KC321, is substantially equivalent in intended use to the legally marketed device, Dimension Vista® ENZ 2 CAL, KC320, based on the information described above.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics, Inc.
c/o Ms. Anna Marie K. Ennis
Senior Regulatory Affairs & Compliance Mgr.
500 GBC Drive, PO Box 6101
Newark, Delaware 19714-6101

Re: k103612
Trade Name: Dimension Visa ENZ 2 CAL
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIX
Dated: December 8, 2010
Received: December 9, 2010

JAN 25 2011

Dear Ms. Ennis

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

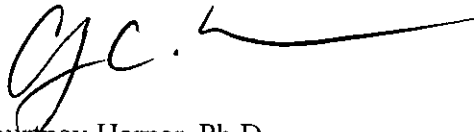
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'GHC', followed by a long horizontal line extending to the right.

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K103612

Device Name: Dimension Vista® ENZ 2 CAL

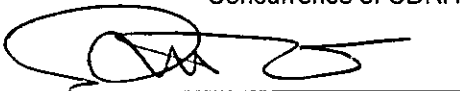
Indications for Use:

The ENZ 2 CAL is an *in vitro* diagnostic product for the calibration of Alanine Aminotransferase (ALT and ALTI) and Aspartate Aminotransferase (AST) on the Dimension Vista® System.

Prescription Use <u>XX</u> (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use <u> </u> (21 CFR 801 Subpart C)
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K103612